REMARKS

Claim Amendments

Claim 21, 48, 51 and 52 have been amended and claims 46, 47, and 56 have been cancelled. Applicants noticed that claim number 55 was inadvertently skipped and was never used. However, this should have no bearing as the last claim number presently pending is claim 54. Claims 21, 42-45 and 48-54 are currently pending. The present claims amendments add no new matter and support for the amendments is discussed below.

Claim rejections

Rejection of claim 21 under 35 U.S.C. 112, first paragraph

The Examiner has rejected claim 21 as not enabled. In claim 21 the heavy variable chain is described as comprising a CDR3, CDR2 and CDR1 having SEQ ID NO:8, 115, and 114, respectively. The claim has been amended to also recite a binding function as required by the Examiner. Thus, the presently amended claims contain both a structure and function limitation as it has been amended to recite "wherein the peptide or polypeptide binds one or more cell types selected from the group consisting of leukemia cells and cells expressing glycocalicin." Support for this amendment can be found in Examples 1-3 where it shows that that the Y1 clone was identified by biopanning against platelets and AML cells. Further, on page 70, Table 6 shows that Y1 can bind to AML, CML, B-CLL, B-ALL, multiple myeloma and T lineage leukemia cells. On page 80, Table 7 shows that Y1 scFv binds to monocytes and platelets and red blood cells. On page 84, Table 9, it is shown that Y1 binds to various hematopoietic cell lines with various affinities. Accordingly, applicants submit that the present claim amendment renders this ground of rejection moot and accordingly, applicants respectfully request withdrawal of this rejection.

Provisional double patenting rejection over claim 29 of co-pending Application No: 10/029,988

The Examiner has provisionally rejected claim 21 over claim 29 of co-pending Application No: 10/029,988. As this is a provisional double patenting rejection, Applicants

respectfully note that once the co-pending application issues, if necessary at that time, a terminal disclaimer will be filed in the appropriate application.

Objection to the Disclosure

The Examiner has objected to the disclosure as Table 10 contained a spelling error. The present amendment has corrected "Ali" to the correct "Ala." Support for this amendment can be found on page 31 of the originally filed specification. On page 31, the correct amino acid sequence for the VH-CDR3 of Y1 is provided in the enclosed box (as "MRAPVI") in the sequence listing of paragraph 129. Thus, it is clear that Ali should have been Ala as it is noted as "A," which is the one letter amino acid identifier for alanine. Accordingly, applicants respectfully request withdrawal of this ground of rejection.

Rejection of claim 52 under 35 U.S.C. 112, second paragraph

The Examiner has rejected claim 52 stating that it lacked antecedent basis for reciting "the scFv." Claim 52 has been amended to delete the term "scFv," thus rendering this ground of rejection moot. Accordingly, applicants respectfully request withdrawal of this ground of rejection.

Rejection of claims 52 and 56 under 35 U.S.C. 112, first paragraph

The Examiner has rejected claims 52 and 56 as containing new matter. Claim 56 has been cancelled. Regarding claim 52, support for this claim can be found in the originally filed specification. Applicants respectfully note that claim 52 does not recite a polynucleotide consisting of SEQ ID NO:8 (CDR3) and SEQ ID NO: 115 (CDR2) and SEQ ID NO: 114 (CDR1), further comprising a light chain variable region consisting of SEQ ID NO:7, as incorrectly understood by the Examiner (cf outstanding office action, page 5, item 13, second paragraph, 2nd sentence). Rather, since claim 52 is dependent on both claims 21 and 42, it encompasses a peptide or polypeptide comprising an Fv, wherein the Fv comprises a heavy chain variable region and a light chain variable region, and wherein the heavy chain variable region comprises CDR3, CDR2 and CDR1 regions consisting of SEQ ID NOS: 8, 115 and 114, respectively, and wherein the light chain variable region consists of SEQ ID NO:25.

Recitation in antecedent claim 21 of "comprising" (in line 1) and "comprises" (in lines 2 and 5) renders claim 52 as encompassing a peptide that: 1) may have sequences in the Fv that are in addition to and/ or in combination with the recited heavy chain variable region and the light chain variable region (e.g. leader, spacer, tag); and 2) may have sequences in the heavy chain variable region that are in addition to and/ or in combination with recited CDRs.

Further, paragraphs 129 and 186 of the filed specification provide support for claim 52, since the scFv molecules disclosed therein include sequences (e.g. leader, spacer, tag), which are neither a heavy chain variable region or a light chain variable region, and the heavy chain variable regions therein includes sequences that flank SEQ ID NO:8 (CDR3), SEQ ID NO: 115 (CDR2) and SEQ ID NO: 114 (CDR1).

In paragraph 129, CDR1 is located at amino acid 53-57 and is SEQ ID NO:114. The CDR2 is located at amino acid 72-88 and is SEQ ID NO: 115. The CDR 3 is located at amino acid 121-126 and is SEQ ID NO:8. The light chain variable region is found at amino acid 153-263 and is SEQ ID NO:7. Further, paragraph 130 describes the Y1 scFV construct shown in paragraph 129 and indicates that the VH and VL regions are joined by a flexible spacer, which is shown in italics in the sequence, and indicates that the VL region follows the spacer. Paragraph 156 states that the VL chain has a sequence of SEQ ID NO:7. Matching the sequences provided in the sequence listing with the sequence of paragraph 129, one can see that a VL of SEQ ID NO:7 is indeed present in a construct where the CDR 1, 2 and 3 are SEQ ID NO: 114, 115, and 8, respectively. Thus the specification clearly shows and provides support for a polypeptide that has a VL chain of SEQ ID NO:7, and a CDR 1, 2 and 3 having SEQ ID NO: 114, 115 and 8, respectively. Accordingly, applicants respectfully request withdrawal of this ground of rejection.

CONCLUSION

Applicant respectfully requests entry of the present Response and consideration of the above-identified application on the merits. It is believed that the application is in condition for allowance and such action is earnestly requested. If the Examiner wishes to discuss the present application, the Examiner is respectfully invited to contact the undersigned. The Office is authorized to charge any fees or credit any refunds due to Kenyon & Kenyon's Deposit Account No: 11-0600.

Respectfully submitted,
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Dated: Nov. 8, 2005

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